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09/756,125

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EXAMINER

EWOLDT, GERALD R

ART UNIT

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1644

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Art Unit: 1644

### DETAILED ACTION

1. Applicant's amendment and remarks, filed 12/17/07 are acknowledged.
2. Claims 9, 11-14, 16-17, and newly added Claims 19-25 are being acted upon.
3. The specification stands objected to for the following reasons. The attempt to incorporate subject matter into this application by reference to WO 92/19759 remains improper. While Applicant has submitted a certified translation of the document and an appropriate executed declaration, it is unclear where in the WO document the actual support for the subject matter of the amendment is to be found.

Applicant's arguments, filed 12/17/07, have been fully considered but they are not persuasive. Applicant argues that support for the amendments to the instant specification can be found at Tables 2 and 3, and page 53 of the translation.

A review of the WO 92/19759 translation shows that while the  $V_L$  of the instant claims can be found there, one  $V_L$  amongst four, the  $V_H$  of the amendment is not found in Table 3. In particular, FR1 of the  $V_H$  of the amendment appears to be found in the  $V_{HPM-1}$  antibody, while other regions are found in the  $RV_{Ha}$  antibody, and the FR3 region of the amendment is not found in any of the  $V_H$ 's. And it is not clear that the document teaches the mixing and matching of the  $V_L$ 's and  $V_H$ 's. Regarding the  $C_k$  and  $C_y$  of page 58, first, the cite discloses a DNA vector and not an antibody, and additionally, only  $C_{y1}$  DNA is disclosed. Finally note that the specification discloses that the antibody employed in the method of the instant claims was originally produced by Hirata et al. (1989). A review of the reference reveals that it discloses a single antibody named PM-1.

Applicant offers Appendix A for clarification of the issues.

Applicant is advised that Appendix A should be reviewed for possible typographical errors as the instant application is 09/756,125, not 09/156,125, and U.S. Patent No. 5,795,965 is unrelated to the instant application.

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Applicant offers a 1.132 declaration stating that singulars and plurals are not differentiated in the Japanese language.

The declaration is noted, however, the issues set forth above require the maintaining the objection.

Applicant argues that even if PM-1 is a specific murine monoclonal antibody, it is well known that many possible antibodies can result from the process of "humanizing" a murine antibody, reflecting the myriad choices available to make a chimeric construct.

While Applicant's argument may be true the instant specification fails to describe a family of humanized antibodies.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 11-14, 16-17 and newly added Claims 19-25 stand/are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: the humanized PM-1 antibody comprising the sequences of SEQ ID NOS:2-16 as set forth in Claims 9, 13, 19, and 22.

Applicant is advised that, as the amendment to the specification is improper, as set forth in Section 3 above, the new claims are also improper and thus, comprise the introduction of new matter into a claims.

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Applicant's arguments, filed 12/17/07, have been fully considered but they are not persuasive. Applicant argues that they were in possession of that which was described in the references in question.

See section 3 above regarding the examiner's position on what the references actually describe.

Applicant again cites *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006) and *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2006).

It remains the Examiner's position that case law cannot provide an adequate written description for the claimed invention. And note that Applicant is claiming more than mere amino acid sequences, i.e., a method employing combinations of amino acid sequence as well as generic C regions.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

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9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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